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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,187	01/23/2000	Preet M. Chaudhary	USTD:0680	6849

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/490,187	CHAUDHARY, PREET M.	
	Examiner	Art Unit	
	Sean R McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 36-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claimed invention is drawn to the detection of the presence or predisposition to an ectodermal disorder. The method includes detection of a TAJ gene or gene product in a cell that has been predetermined to be at elevated risk of having or being predisposed to a particular disorder. The methods include the detecting of TAJ variants and TAJ truncates, the detection of an ectodermal dysplasia syndrome and specifically for the detection of Clouston syndrome. The claimed methods require the detection of a TAJ gene or gene product in a cell that has been **predetermined** to be at elevated risk of having or being predisposed to a **particular ectodermal** disorder, correlating the presence of the TAJ gene or gene product with a presence or predisposition to the ectodermal disorder where the gene or gene product is a **variant correlated** with the presence or predisposition to the [particular] ectodermal disorder.

The specification discloses SEQ ID NOs:1 and 2 which corresponds to the cDNA and amino acid sequence of human TAJ and also discloses, in Table 1, 13 mutants of TAJ that result in TAJ truncates which are "[e]xemplary TAJ gene lesions shown to be

associated with an ectodermal dysplasia." The specification also discloses 13 specific antibodies and 13 specific antisense oligonucleotides that are specific for those same 13 mutants in Table 2. The specification discloses that there are over 150 different ectodermal dysplasia syndromes, and also asserts that ectodermal disorders may arise from temporal, developmental, quantitative or qualitative TAJ misexpression and that a wide variety of causalities may effect such misexpression such as genetic lesions or mutations of the gene itself or direct or indirect TAJ regulatory sequences, the misexpression of genes or gene products which may in turn regulate TAJ expression or TAJ function. . .etc. It is noted that the claims are so broad as to embrace any ectodermal disorder, for example. It is clear that there is a vast range of potential causalities for a wide range of ectodermal disorders that may be associated with TAJ such that the detection of a TAJ or TAJ misexpression in association with the causality will detect an ectodermal disorder or a disposition thereto. It is noted that even the 13 specific mutations are not disclosed to be associated with any particular disorder including the specifically recited Clouston syndrome. The specification fials to, for example show any correlation of any particular TAJ variant with any particular ectodermal disorder. The specification also fails to show that the prior art shows the existent of any known correlation such as a clinical correlation of any such association of any particular TAJ variant with any particular ectodermal disorder. The claims require that the cells be predetermined to be predisposed or having a particular ectodermal disorder, but as asserted above the range of disorders included within that scope is quite large where the specification does not disclose any particular ectodermal disorder

to be associated with any particular TAJ misexpression nor does the prior art. One is lefy with only trial and error experimentation to determine what/if such correlations exist.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.) The specification clearly fails to disclose what mutations correlate to any particular disorder.

With the exception of the 13 truncation mutants the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation that may be used as a detection means for the detection of the presence or predisposition to a particular ectodermal disorder. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

The specification fails to describe any structural features common to a genus of TAJ variants that would impart the function of causing one to have or be associated with one having or being predisposed to any particular ectodermal disorder, for example. The specification fails to provide a representative number of species within the genus to constitute a description of the full genus. The claimed invention is essentially an invitation for one in the art to find TAJ mutations that might be correlated with having or being indicative of being predisposed to a ectodermal disorder where the specification fails to exemplify even one such correlation other than the purported association of the 293 truncation in example IV.

The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant's arguments and the opinion declaration of Richard Gaynor filed 10/04/04 have been fully considered but they are not persuasive nor provide evidence of sufficient weight to overcome the rejection above.

Applicant asserts that the specification provides a variety of suitable detection methodologies and a panel of exemplary TAJ specific probes and further assert that step (b) involves no more than correlating the detected TAJ gene or gene product with an ectodermal disorder.

It is the examiners position that the 13 specific antibodies (disclosed by name only) and the 13 allele specific antisense oligonucleotides are targeted to 13 specific truncates of TAJ that have not been described in the specification as being associated with any particular ectodermal disorder. The claims indeed require that the detection of a TAJ gene or gene product be capable of providing a detection of or predisposition to a **particular** ectodermal disorder. There is clearly no disclosure of the structure of any other detection means for any particular TAJ variant. The specification only provides trial and error means to make such detection means.

Applicant asserts that the correlation step, in "many cases" "entails no more than cross referencing to a known clinical correlate." There is no disclosure in the specification or in the prior art of record that indicates where one in the art might find such a known correlate, for example. It appears that it is up to one in the art to make such correlations while the claim requires that the TAJ variant be already correlated.

Applicant argues that one in the art need not know many correlations of many ectodermal dysplasias with many TAJ mutations. Applicant asserts that the practitioner only needs to know one, for example. The claimed invention is clearly much broader in scope that applicant asserts since it is not and clearly not limited to one variant and one mutation but a vast range. Further it is the position of the examiner that the specification has failed to show even one, for example. Applicant asserts that there is no comprehensive foreknowledge required and asserts that the cell comes from a patient that has a required presentation to which the practitioner is not blind. The claimed method embraces, for example, that the host of the cell be predetermined to be at risk of being predisposed to an ectodermal disorder. There is no requirement that there be a clinical presentation of anything.

Applicant argues that one in the art is not required to find any TAJ mutations that might be correlated with an ectodermal disorder. It is the position of the examiner that if the specification nor the prior art have taught the correlation of TAJ mutants then one in the art would be required to do so to practice the instant invention.

The opinion declaration of Richard Gaynor provides no evidence but points to the specification for support of the claimed invention. The declaration asserts that the

specification provides the sequence of a wild type TAJ and asserts that the mutations could be of this sequence.

The assertion that the mutation of this sequence [the disclosed wild type sequence] could be a source of mutation does not describe what mutations in particular would be associated/correlated with any particular ectodermal disorder. The specification only provides trial and error methodologies to make such determinations.

The declaration points out that such methodologies are described in the specification. And also asserts that one only need make the correlations on their own or refer to some undisclosed known clinical correlate.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sean R McGarry
Primary Examiner
Art Unit 1635

SRM